



National Institutes of Health  
Office of Extramural Research



# HHS Commercialization Readiness Pilot Program (CRP) Informational Webinar

December 2, 2015

**Matthew Portnoy, Ph.D.**

SBIR/STTR Program Manager

**Stephanie Fertig, MBA**

SBIR/STTR Program Coordinator (NINDS)





- Commercialization Readiness **Pilot** Program (CRP) Authority
- Basics of CRP
- HHS Funding Opportunities
- Pre-Submitted Questions
- Open Q&A

<https://sbir.nih.gov/funding#crp>





- Up to 10% of Agency SBIR program (NIH + CDC SBIR in FY15 ~ 698M = max ~\$70M for CRP)
  - A) for awards for technology development, testing, evaluation, and commercialization assistance for SBIR and STTR Phase II technologies; or
  - B) to support the progress of research, research and development, and commercialization conducted under the SBIR or STTR programs to Phase III.
- CRP awards can be up to 3X Phase II Budget guideline.
  - (Phase II Guideline = \$1M, CRP max = \$3M total costs)
- PILOT authority to issue competing CRP awards **expires 9/30/2017** (end of reauthorization)



- 2 CRP Grant Funding Opportunity Announcement (FOA) released on November 2, 2015
  - Only some NIH/CDC Institutes and Centers are participating
  - Not all NIH/CDC Institutes and Centers are on both FOAs
- New NIH Activity code- SB1
- CRP is neither a Phase I nor a Phase II
- CRP Applicant must be a SBIR-eligible Small Business
- CRP Applicant must have received an HHS SBIR or STTR Phase II or IIB.

**Special instructions in the FOAs  
READ THE FOAs CAREFULLY!**



<https://sbir.nih.gov/funding#crp>

**Commercialization  
Readiness Pilot (CRP)  
Program Solicitations**

PAR-16-026 (Technical Assistance)

PAR-16-027 (Technical Assistance  
and Late Stage Development)

**Standard Receipt Dates:**



September 5



January 5



April 5



- PAR-16-026 SBIR/STTR Commercialization Readiness Pilot (CRP) Program: Technical Assistance (SB1)  
<http://grants.nih.gov/grants/guide/pa-files/PAR-16-026.html>
- PAR-16-027 SBIR/STTR Commercialization Readiness Pilot (CRP) Program: Technical Assistance and Late Stage Development (SB1)  
<http://grants.nih.gov/grants/guide/pa-files/PAR-16-027.html>



- Both Use Standard SBIR due dates
- January 5, April 5, September 5, 2015
- January 5, April 5, September 5, 2016
- January 5, April 5 (last due date), 2017
- Expires April 6, 2017
- No separate AIDS dates
- Letters of Intent:
  - Optional
  - Due 30 days before each deadline
  - Sent to Dr. Kristin Kramer (info in FOA Notice)



- **Applicants can use ASSIST or downloadable forms.**
- Phase II predicate could be a grant or contract.
- Phase IIB predicate will be a grant.
- All CRP awards are GRANTS.
- On the SBIR/STTR Information Form
  - **Program Type:** Check "SBIR" *regardless* of whether the Phase II or IIB predicated the CRP application was a SBIR or STTR award.
  - **SBIR/STTR Type:** Check "Phase II" as CRP awards are follow-on awards for Phase II or IIB awards.
  - Answer questions 8 and 9 as specific to the SBIR program.



- SBC must meet and continue to meet SBIR company eligibility requirements on # employees ownership etc.
- CRP PI must (like SBIR) be primarily employed by SBC at time of and during an award.
- ***SBC may subcontract a substantial portion of its CRP award to third parties through consultant and contractual arrangements.***
  - The SBC must perform a substantive role in the conduct of the planned research
  - The SBC should provide appropriate oversight of all scientific, programmatic, financial, and administrative matters related to the grant
  - Cannot merely serve as a conduit of funds to another party or parties



## PAR-16-026: Technical Assistance CRP

The purpose of this Funding Opportunity Announcement (FOA) is to encourage applications from small business concerns (SBCs) to the newly authorized Commercialization Readiness Pilot (CRP) program. The FOA aims to facilitate the transition of previously funded SBIR and STTR Phase II projects to the commercialization stage by **providing additional support for technical assistance not typically supported through Phase II or Phase IIB grants or contracts. This may include preparation of documents for a Food and Drug Administration (FDA) submission, development of an intellectual property strategy and/or planning for a clinical trial.** Although a significant amount of the work in a CRP award may be subcontracted to other institutions, the SBC is expected to maintain oversight and management of the R&D throughout the award.





- **Technical Assistance Only**
- <http://grants.nih.gov/grants/guide/pa-files/PAR-16-026.html>
- NIH (8 ICs) + CDC (1 CIO)
  - National Institute of Neurological Disorders and Stroke ([NINDS](#))
  - National Heart, Lung, and Blood Institute ([NHLBI](#))
  - National Institute on Aging ([NIA](#))
  - National Institute on Alcohol Abuse and Alcoholism ([NIAAA](#))
  - National Institute of Biomedical Imaging and Bioengineering ([NIBIB](#))
  - National Institute of Diabetes and Digestive and Kidney Diseases ([NIDDK](#))
  - National Institute of Environmental Health Sciences ([NIEHS](#))
  - National Center for Advancing Translational Sciences ([NCATS](#))
  - CDC/National Center for Chronic Disease Prevention and Health Promotion ([NCCDPHP](#))





- Budgets up to **\$300,000** total costs, for the entire project period, may be requested except for CRP applications associated with the Institutes listed below:
  - National Heart, Lung, and Blood Institute (NHLBI): total funding support may not exceed **\$50,000\***
  - National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK): total funding support may not exceed **\$150,000**
  - National Institute of Environmental Health Sciences (NIEHS): total funding support may not except **\$200,000**
- Max budget period is 2 years.



\*See <http://grants.nih.gov/grants/guide/notice-files/NOT-HL-15-283.html>



Topic areas appropriate for this FOA include, but are not limited to the following:

- **Development of regulatory strategy**, including assembling the documentation needed for the Investigational New Drug (IND) or Investigational Device Exemption (IDE) submission to the Federal Drug Administration (FDA)
- **Design and planning for a clinical trial** including: Preparation of documents required to support a clinical trial (e.g., case report forms, pharmacy manual, study coordinator manual, monitoring plan), preparation of clinical trial protocol, and preparation of investigator's brochure
- **Development of an intellectual property strategy**, including analysis of the patent landscape in the US and abroad.
- **Technical assistance associated with manufacturing**
- **Other technical assistance** offered through a third party technical assistance provider, including market research





## PAR-16-027: Technical Assistance and Late Stage Development CRP

The purpose of this Funding Opportunity Announcement (FOA) is to encourage applications from small business concerns (SBCs) to the newly authorized Commercialization Readiness Pilot (CRP) program. The FOA aims to facilitate the transition of previously funded SBIR and STTR Phase II projects to the commercialization stage by **providing additional support for technical assistance and later stage research and development (R&D) not typically supported through Phase II or Phase IIB grants or contracts. This may include independent replication of key studies, Investigational New Drug (IND)-enabling studies, clinical studies, manufacturing costs, regulatory assistance, or a combination of services.** Although a significant amount of the work in a CRP award may be subcontracted to other institutions, the SBC is expected to maintain oversight and management of the R&D throughout the award.





- **Technical Assistance and Late Stage Development**
- <http://grants.nih.gov/grants/guide/pa-files/PAR-16-027.html>
- NIH (9 ICs)
  - National Institute of Neurological Disorders and Stroke ([NINDS](#))
  - National Eye Institute ([NEI](#))
  - National Institute on Aging ([NIA](#))
  - National Institute on Alcohol Abuse and Alcoholism ([NIAAA](#))
  - National Institute of Allergy and Infectious Diseases ([NIAID](#))
  - National Institute of Arthritis and Musculoskeletal and Skin Diseases ([NIAMS](#))
  - National Institute of Dental and Craniofacial Research ([NIDCR](#))
  - National Institute of Diabetes and Digestive and Kidney Diseases ([NIDDK](#))
  - National Institute of Mental Health ([NIMH](#))



- Budgets up to **\$3,000,000** total funding support (direct costs, indirect costs, fee) for the entire budget period may be requested expect for the CRP applications associated with the Institutes listed below:
  - National Institute of Allergy and Infectious Disease (NIAID): Budgets may not exceed **\$1,000,000** total funding support **in any year**.
  - National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS): Budget may not exceed **\$400,000** total funding support **in any year**.
  - National Institute of Dental and Craniofacial Research (NIDCR): Budget may not exceed **\$1,000,000** total funding support **in any year**.
  - National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK): Budgets may not exceed **\$1,000,000** **total funding support**.
  - National Eye Institute (NEI): Budgets may not exceed **\$500,000** total funding support **in any year**.

**Max budget period is 3 years.**





## Technical Assistance

- **Development of regulatory strategy**, including assembling the documentation needed for the Investigational New Drug (IND) or Investigational Device Exemption (IDE) submission to the Food and Drug Administration (FDA)
- **Design and planning for a clinical trial** including: Preparation of documents required to support a clinical trial (e.g., case report forms, pharmacy manual, study coordinator manual, monitoring plan), preparation of clinical trial protocol, and preparation of investigator's brochure
- **Development of an intellectual property strategy**, including analysis of the patent landscape in the US and abroad
- **Technical assistance associated with manufacturing**
- **Other technical assistance** through a third party technical assistance provider, including market research.





## Late Stage Research and Development Activities

- Independent replication/confirmation of key studies
- Activities to ensure compliance with applicable FDA requirements and GMP (Good Manufacturing Practice) standards
- Activities to bring the development process under Design and Quality Systems Control
- Animal studies to develop surgical techniques relevant to a device
- *In vitro* and animal testing to meet FDA recognized ISO/ASTM Standards
- Optimization of the device design with respect to the human functional anatomy
- Device, software, and firmware design verification and validation activities
- GLP compliant large animal studies





- Identification of the most simple, reliable, and cost effective device configuration for more advanced clinical trials and eventual market approval
- Process optimization and synthesis, including development of analytical methods to determine drug purity and development of a clinical trial formulation
- IND-enabling studies, including toxicology
- Chemistry, Manufacturing, and Control (CMC) activities for IND-enabling pharmacology/toxicology tests
- Pharmacokinetic/ADME (absorption, distribution, metabolism, excretion) studies
- Tumorigenicity, immunogenicity, mutagenicity and teratogenicity evaluations





- GMP manufacturing of clinical trial supplies
- Optimization of delivery systems
- Development and validation of biochemical assays required for clinical trials (e.g., pharmacokinetic, pharmacodynamic, and/or immunogenicity assays)
- Clinical studies and clinical trials
  - NIDDK and NEI will accept clinical trials
  - NINDS, NIAID, NIDCR, NIAMS, NIMH, and NIAAA will not accept clinical trials through the CRP
  - **Contact your program official** if you are proposing a clinical trials



- See Section IV/2 of each FOA
  - [http://grants.nih.gov/grants/guide/pa-files/PAR-16-026.html#\\_Section\\_IV\\_Application](http://grants.nih.gov/grants/guide/pa-files/PAR-16-026.html#_Section_IV_Application)
  - [http://grants.nih.gov/grants/guide/pa-files/PAR-16-027.html#\\_Section\\_IV\\_Application](http://grants.nih.gov/grants/guide/pa-files/PAR-16-027.html#_Section_IV_Application)
- Must still provide SBA SBC Registry PDF
- If VCOC SBC, must still provide VCOC certification
- R&R Budget
  - Filing fees associated with filing patents or FDA submissions are not permissible.
  - The SBC must perform a substantive role in the conduct of the planned research and not merely serve as a conduit of funds to another party or parties. This includes being able to provide appropriate oversight of all scientific, programmatic, financial, and administrative matters related to the grant...





- PHS 398 Research Plan
  - Additional Instructions for Significance, Innovation, and Approach
  - Letters of support are important!
- SBIR/STTR Information Form
  - Read carefully for checking SBIR and Phase II boxes
  - Additional Instructions for the Commercialization Plan
  - Answer Questions 8 and 9 specific to SBIR

**Special instructions in the FOAs  
READ THE FOAs CAREFULLY!**



- Special CRP panel/s convened by CSR
- SRO contact are Dr. Kristin Kramer and Gene Carstea (changed- Notice to be issued soon)
- Review criteria (Section V) have been changed specifically for CRP.
- Review criteria map to instructions in Section IV.2.
  - Additional Review Criteria on Commercialization Plan and Fundraising Plan
  - Progress on Phase II/IIB

**Special instructions in the FOAs  
READ THE FOAs CAREFULLY!**



- **Talk to an NIH Program Officer** about your application and **SUBMIT EARLY** (days not hours and minutes)!
  - Program Officer contact information found in the NIH SBIR/STTR Solicitation on <http://sbir.nih.gov>
  - Questions about who to contact? Email [sbir@od.nih.gov](mailto:sbir@od.nih.gov)







- Does the Phase II have to be funded before the CRP application can be submitted?
- Can the Phase II and CRP be active at the same time?
- Are the CRP and Phase IIB mutually exclusive?
- If I have a Phase II from an NIH Institute/Center (or another agency) that does not participate can I come in for a project under an Institute/Center that does?



- Could the CRP be submitted by the same PI but from a company (also a small business) other than the company that was a recipient of original Phase I / Phase II funding?
- Would the regulatory assistance and clinical studies needed for the CPT code application be qualified as CRP costs?
- Would the review prioritize the FDA regulatory costs over the reimbursement submission costs?
- Is marketing work allowed?
- Does the CRP follow the SBIR policies associated with work in foreign countries?
- If an Institute (NINDS, NIAAA, NIDDK) participates in both FOAs, which one do I apply to?





**Please Submit  
Questions to the  
Question Box**



### Get Connected!

- Subscribe to the SBIR/STTR Listserv:
  - Email [LISTSERV@LIST.NIH.GOV](mailto:LISTSERV@LIST.NIH.GOV) with the following text in the message body: **subscribe SBIR-STTR your name**
- NIH Guide for Grants and Contracts (weekly notification)  
<http://grants.nih.gov/grants/guide/listserv.htm>
-  Follow us on Twitter: @NIHsbir
- Submit your SBIR/STTR Success Story at: <http://sbir.nih.gov>
- Email: [sbir@od.nih.gov](mailto:sbir@od.nih.gov)

